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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,989	07/24/2003	Kenneth David Reginald Setchell	3515-104	1706

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
PRYOR, ALTON NATHANIEL	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
04/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/625,989	SETCHELL ET AL.	
	Examiner	Art Unit	
	ALTON N. PRYOR	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9-21,25 and 27-36* is/are pending in the application.

4a) Of the above claim(s) *6,7,9-21,25,28 and 30-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,29 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 1/12/10 have been fully considered but they are not persuasive. Previous rejections and other issues not addressed below are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Wldyarinl et al. (Isoflavonoid compounds from Red Clover (Trifollum pretense) Protect from Inflammation and immune Suppression induced by UV Radiation, Photochemistry and Photobiology, 2001, 74(3), pp. 465-470). The reference teaches Isoequol (R-equol) in lotion (carrier). The lotion can be applied topically to treat inflammation (pharmaceutical application). See entire reference.

Response to Applicants' argument

Applicants argue that Widyarini et al. refer to equol and isoequol, Widyarini et al. do not teach a method used to synthesize equol and isoequol. Applicants argue that Widyarini et al. are not clear that they were actually working with equol enantiomers. The Examiner argues that the rejected claims are drawn to compounds and pharmaceutical compositions, not process of producing claims. Based on this fact, Widyarini et al. do not have to teach a specific method of making or purifying equol or isoequol. However, Widyarini et al. do teach that the isoflavones are obtained from

plants (see introduction at page 485), and Widyarini et al. do teach Figure 1 which depicts isoequol and equol. The Widyarini et al. reference enables one to obtain isoflavones such as isoequol from plants. The Widyarini et al. reference also teaches Isoequol (R-equol) in lotion (carrier). This teaching anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4,5,29,34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widyarini et al. as applied to claims 1 and 2. See 102 rejection above. The reference teaches all that is recited in claims 4,5,29,34-36 except for the purity level of the R-equol in the composition and the specified conjugates. An artisan provided the teaching of Wldyarinl would have been able to optimize the purity of R-equol through routine experimentation even to the level of 90 or 96% purity. In the absence of unexpected data, it would have been obvious to employ any conjugated of the instant equol including those recited in the instant claims. One would have been motivated to do this because equol and conjugates thereof would have been expected to have been equally effective.

Response to Applicant's argument

Applicants argue that since the Widyarini et al. reference fails to enable the instantly claimed R-equol compositions, it also fails to enable the instantly claimed conjugates thereof. Widyarini et al. refer to equol and isoequol, Widyarini et al. do not teach a method used to synthesize equol and isoequol. Applicants argue that Widyarini et al. are not clear that they were actually working with equol enantiomers. The Examiner argues that the rejected claims are drawn to compounds and pharmaceutical compositions, not process of producing claims. Based on this fact, Widyarini et al. do not have to teach a specific method of making or purifying equol or isoequol. However, Widyarini et al. do teach that the isoflavones are obtained from plants (see introduction at page 485), and Widyarini et al. do teach Figure 1 which depicts isoequol and equol. The Widyarini et al. reference enables one to obtain isoflavones such as isoequol from plants. The Widyarini et al. reference also teaches Isoequol (R-equol) in lotion (carrier).

Note, Widyarini et al. teach a composition comprising R-equol and lotion without the mention of S-equol. Such teaching suggest that the composition contains essentially pure R-equol which may read on the instantly claimed R-equol enantiomeric purity range of 90 to 96% absent a showing to the contrary. Like compounds and salts thereof are expected to exhibit similar activity, the R-equol and conjugates thereof would also be expected to yield similar activity. An artisan in the field would expect this because the activity would arise from the compound core structure and the R-equol core structure, not the salt thereof and conjugate thereof respectively.

Claims 1,2,4,5,29,34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvira et al (Molecular modeling study for chiral separation of equol enantiomers by beta-cyclodextrin, vol. 240, issues 1-5, 1999, pp. 101-108). Alvira teaches the separation of R-equol from the S-equol, which meets the limitation of a composition comprising R-equol. Alvira teaches cyclodextrin (carrier) is used in separation process. See reference. Note R-equol is the only required component for the composition claims. Alvira does not teach that the combination of equol and cyclodextrin is pharmaceutical. However, in a claim drawn to a composition a statement to intended use (pharmaceutical) has little patentable significance. In addition, it is well known that cyclodextrin can be used in pharmaceutical compositions which makes it obvious to manufacture the combination of equol and cyclodextrin. Alvira teaches all that is recited in claims 4 and 5 except for the R-equol being present in 90 or 96% enantiomeric purity. An artisan provided the technique of Alvira would have been able to optimize the purity of R-equol through routine experimentation even to the level of 90 or 96% purity. Alvira teaches all that is recited in claim 29 except for the specified conjugates. The rational is that in the absence of unexpected data, it would have been obvious to employ any conjugated of the instant equol including those recited in the instant claims. One would have been motivated to do this because equol and conjugates thereof would have been expected to have been equally effective.

Response to Applicants' argument

The Applicants argue that the Alvira reference refers to theoretical studies and that no actual composition is suggested or prepared in the Alvira reference. Applicants argue that no indication that enantiomeric equol even could be made in the quantities that would be useful in formulating the compositions claimed. The Applicants argue that the Alvira reference does not disclose or suggest the separation of R-equol for S-equol, how to obtain a racemic equol, a pharmaceutical composition or any formulation that consist essentially of R-equol plus a pharmaceutical adjuvant, carrier or excipient or any composition comprising pure R-equol or any composition for oral or topical application comprising R-equol which is substantially free of S-equol. Applicants argue that the Office for decades has recognized claims to compounds and claims to pharmaceutical compositions are patentability distinct (Schering Corp. v. Geneva Pharm., Inc. , 339 F.3d 1373, 1381 Fed. Cir. 2003). Applicants also provide a declaration by Dr. Jackson which demonstrates that R-equol show unexpected results in comparison to the S-equol and racemic in specific applications. The Examiner argues that terms/phrases such as "pharmaceutical composition" and "for oral consumption or topical application" refer to intended use. While the Examiner agrees that claims drawn to compounds and pharmaceutical compositions are patentability distinct, the Examiner reiterates that in claims drawn to compositions a statement to utility has no or little patentable significance. The Examiner further argues that Alvira teaches resolving the R and S isomers of equol in cyclodextrin; therefore, the final composition would consist essentially of R-equol in cyclodextrin which would be substantially free of the S-equol. Alvira teaches the separation of R-equol from the S-equol, which meets the limitation of

a composition comprising R-equol. Alvira teaches cyclodextrin (carrier) is used in separation process. See reference. No enantiomeric equol quantities are set forth in the independent claims. Although the declaration provides different/unexpected results for the R-equol with respect to the S-equol and the racemic, Alvira has already shown that the R and S isomers of equol are resolvable. Therefore, the activity of the resolved R isomer in cyclodextrin and the resolved S isomer in cyclodextrin set forth by the Declaration would automatically be present as a chemical property of each cyclodextrin-equol mixture. For this reason, Alvira reads on instant claims drawn to a composition consisting essentially of R-equol plus cyclodextrin.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/
Primary Examiner, Art Unit 1616